



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mac Medical
C/O Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

JAN 10 2017

Re: K080609

Trade/Device Name: SWC/DWC Warming Cabinets
Regulation Number: 21 CFR 890.5950
Regulation Name: Powered Heating Unit
Regulatory Class: Class I
Product Code: LHC
Dated: May 30, 2008
Received: June 2, 2008

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of June 13, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 080609

Device Name: SWC/DWC (Various Models) Warming Cabinets

Indications For Use:

These warming cabinets are designed to store, warm, and maintain the recommended temperature of irrigation solutions prior to use.

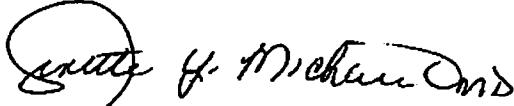
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X.
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Jennifer F. Michael, M.D.
(Division Sign-Off)

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Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 080609

MAC Medical

820 S Mulberry St.

Millstadt, IL 62260

Phone (618) 476-3550

Fax (618) 476-3337

Date prepared: May 25, 2008

Contact: Dennis Cooper

1. Identification of the Device:

Proprietary-Trade Name: SWC/DWC (Various Models) Warming Cabinets

Classification Name: Warmer, irrigation solution cabinet

Product Code ~~LIC~~ LDQ

Common/Usual Name: Irrigation Warmer

2. Equivalent legally marketed devices: K993797, Enthermics Medical Systems Fluid Warming Cabinet

3. Indications for Use (intended use) These warming cabinets are designed to store, warm, and maintain the recommended temperature of irrigation solutions prior to use.

4. Description of the Devices: These devices are 120 or 220 V Ac powered warming cabinets designed to store, warm, and maintain the recommended temperature of irrigation solutions prior to use. The particular cabinet configuration can be deduced from its model number:

SWC = Single Warming Cabinet.

DWC = Dual Warming Cabinet.

G = Glass Door

The temperature ranges and capacities vary according to model but all have:

Adjustable Temperature Range

Digital Control

Dual Display

Push Button Operation

Rapid Warm Time

High Accuracy.

5. Safety and Effectiveness, comparison to predicate device. The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Characteristic	K993797, Enthermics Medical Systems Fluid Warming Cabinet	SWC/DWC (Various Models) Warming Cabinets
Intended Use:	Warming Irrigation Solutions	<u>SAME</u>
User Interface	Digital Display	<u>SAME</u>
Power Source	AC Line	<u>SAME</u>
Door opening	Left or right hand	<u>SAME</u>
Door style	Glass	Glass or Stainless
Construction	Stainless Steel	<u>SAME</u>
Safety	UL Listed	<u>SAME</u>

7. Conclusion

After analyzing bench and standards testing data, it is the conclusion of MAC Medical that the SWC/DWC (Various Models) Warming Cabinets are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.